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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/990,441	11/16/2001	Avi J. Ashkenazi	P2730P1C47	2350

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EXAMINER

HAMUD, FOZIA M

ART UNIT

PAPER NUMBER

1647

DATE MAILED: 10/01/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/990,441	ASHKENAZI ET AL.	
	Examiner	Art Unit	
	Fozia M Hamud	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 August 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 119-124 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 119-124 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Applicant's preliminary amendment canceling claims 1-118 and adding new claims 119-124, filed on 16 November 2001 is acknowledged.

Thus claims 119-124 are pending and under consideration.

2. **Priority:**

2a. Based on the information given by Applicants and an inspection of the patent applications, the Examiner has concluded that the subject matter defined in this application is supported by the disclosure in application serial no. 09/941,992 filed on 28 August 2001, because, EXAMPLE 160 (Assay #111; Chondrocyte proliferation assay which demonstrates that the polypeptide that the claimed antibodies bind to, induces the proliferation of chondrocytes), which provides a specific and substantial asserted utility or a well established utility for the claimed antibodies is disclosed on page 531 of Application no. 09/941,992. However, it does not appear that any of the other prior applications disclose this assay. Accordingly, the subject matter defined in claims 119-124, is afforded an effective filing date of 28 August 2001, which is the filing date of the U.S application No. 09/941,992.

Should the applicant disagree with the examiner's factual determination above, it is incumbent upon the applicant to provide the serial number and specific page number(s) of any parent application filed prior to 08/28/01, which specifically supports the particular claim limitation for each and every claim limitation in all the pending claims which applicant considers to have been in possession of and fully enabled for prior to 08/28/01.

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Specification:

3a. The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

Information Disclosure Statement:

4a. References A1 and A2, cited on the PTO-1449 form submitted by Applicants on 31 May 2002 have not been considered, because they do not comply with 37 CFR 1.98(a)(2) requirements, since they fail to identify each publication by author and publication date. Applicant is advised that the date of submission of any item of information or any missing element(s) will be the date of submission for purposes of determining compliance with the requirements based on the time of filing the IDS, including all "statement" requirements of 37 CFR 1.97(e). See MPEP § 609 C(1).

Claim rejections-35 USC § 112, second paragraph:

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 119 and 124 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

5a. Claim 119 is drawn to an antibody that binds to a polypeptide, and claim 124 is drawn to an antibody that specifically binds to the same polypeptide.

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However, it is unclear how the antibody claimed in claim 119 differs from the one claimed in claim 124. Therefore, absent definition of "specific binding" it is not clear what the difference between the two claims is and what each claim is meant to encompass, given that antibody binding is determined by the variable regions structure and is a "specific" event. Appropriate correction is required.

Claim Rejections - 35 U.S.C. §102(b):

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6a. Claims 119-124 are rejected under U.S.C. § 102 (b) as being anticipated by Baker et al (WO9963088; published 09 December 1999).

Baker et al disclose an isolated polypeptide that shares 100% homology to the polypeptide of SEQ ID NO:422 of the instant application and an antibody that binds to said polypeptide, (see figure 304). The antibody disclosed by Baker et al encompasses a monoclonal antibody, a humanized antibody and labeled antibody, (see claims 17-20).

Instant claims 119-124 are drawn to an isolated antibody that binds to the polypeptide of SEQ ID NO:422, wherein the antibody is monoclonal, a humanized antibody or labeled. Therefore, the Baker et al reference meets all the limitations recited in claims 119-124, anticipating said claims, in the absence of any evidence to the contrary.

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7b. Claims 119-124 are rejected under U.S.C. § 102 (b) as being anticipated by Ashkenazi et al (WO200032221; published 08 June 2000).

Ashkenazi et al disclose an isolated polypeptide that shares 100% homology to the polypeptide of SEQ ID NO:422 of the instant application and an antibody that binds to said polypeptide, (see figure 92). The antibody disclosed by Ashkenazi et al encompasses a monoclonal antibody, a humanized antibody and labeled antibody, (see claims 17-20).

Instant claims 119-124 are drawn to an isolated antibody that binds to the polypeptide of SEQ ID NO:422, wherein the antibody is monoclonal, a humanized antibody or labeled. Therefore, the Baker et al reference meets all the limitations recited in claims 119-124, anticipating said claims, in the absence of any evidence to the contrary.

7c. Claims 119-124 are rejected under U.S.C. § 102 (b) as being anticipated by Walker et al (WO200029574; published 25 May 2000).

Walker et al disclose an isolated polypeptide that shares 100% homology to the polypeptide of SEQ ID NO:422 of the instant application and antibodies that bind to said polypeptide, (see SEQ ID NO:17, page 2, lines 29-33, page 16, lines 13-24). The antibody disclosed by Walker et al encompasses a monoclonal antibody, is labeled and is humanized, (see especially pages 16, lines 15-24).

Instant claims 119-124 are drawn to antibody that binds to the polypeptide of SEQ ID N:422, wherein the antibody is labeled, monoclonal and humanized. Therefore, the Walker et al reference anticipates instant claims 119-124, in the absence of any evidence to the contrary.

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Conclusion:

7. No claim is allowed.

Advisory Information:

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Fozia M Hamud whose telephone number is (571) 272-0884. The examiner can normally be reached on Monday, Thursday-Friday, 6:00 am to 4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda G Brumback can be reached on (571) 272-0961. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Fozia Hamud
Patent Examiner
Art Unit 1647
26 September 2004.


JANET ANDRES
PRIMARY EXAMINER